UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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FERRING B.V., FERRING INTERNATIONAL CENTER S.A., AND FERRING PHARMACEUTICALS INC.,

Plaintiffs,

12 Civ. 2650

-against-

SEALED OPINON

ALLERGAN, INC., ALLERGAN USA, INC., ALLERGAN SALES, LLC, SERENITY PHARMACEUTICALS CORPORATION, SERENITY PHARMACEUTICALS, LLC, REPRISE BIOPHARMACEUTICS, LLC, SEYMOUR H. FEIN, AND RONALD V. NARDI,

Defendants.

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Sweet, D.J.

Pending before the Court are several motions filed by Defendants Allergan, Inc., Allergan USA, Inc., Allergan Sales, LLC (collectively "Allergan"), Serenity Pharmaceuticals Corporation, Serenity Pharmaceuticals, LLC (collectively "Serenity"), Reprise Biopharmaceutics, LLC ("Reprise"); Seymour H. Fein ("Fein"), and Ronald V. Nardi ("Nardi" and together with Serentiy, Reprise and Fein, the "Non-Allergan Defendants"), and by Plaintiffs Ferring B.V., Ferring International Center S.A., and Ferring Pharmaceuticals Inc. (collectively, "Ferring" or the "Plaintiffs"). First, Allergan has moved for summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure against Plaintiffs (the "Summary Judgment Motion"). Second, the Non-Allergan Defendants have filed a motion seeking to join in Allergan's motion for summary judgment (the "Joinder Motion"). Third, Allergan has filed a letter seeking to compel Ferring to provide additional corporate testimony regarding Ferring's inventorship claims (the "Motion to Compel"). Fourth, Ferring has filed a letter requesting that the Non-Allergan Defendants be barred from asserting privilege with respect to certain Ferring documents under Non-Allergan Defendants' control and from sharing those documents with Non-Allergan Defendants'

patent prosecution outside counsel (the "Confidentiality Motion").

Upon the conclusions set forth below, the Summary Judgment Motion and the Joinder Motion are granted, and the Motion to Compel and Confidentiality Motion are rendered moot.

This action presents a dispute over the ownership of certain patents involving desmopressin, a synthetic hormone, used to treat disorders related to excessive urine production. According to the Plaintiffs, Fein, Nardi and their companies Serenity and Reprise improperly obtained the patents at issue starting in 2003 and, in selling them to Allergan, violated certain duties and obligation to which Allergan was compliant. According to the Defendants, the Plaintiffs have delayed advancing their claims and this litigation in order to impose the risks and costs of drug development on Allergan and then to obtain patent correction in their favor.

Prior Proceedings & Facts

Familiarity with the prior proceedings and facts as alleged in the initial complaint filed by Ferring on April 5,

2012 is assumed and were set forth in the March 18, 2013 order (the "March 18 Order") granting Defendants' motion to dismiss.

The Motion for Equitable Estoppel and Joinder Motion were filed on April 17, 2015. The Motion to Compel was filed on April 30, 2015. The Confidentiality Motion was filed on May 1, 2015. All four motions were marked fully submitted on May 20, 2015.

The synopsis below, derived from Allergan's Rule 56.1 Statement and Ferring's Response to the 56.1 Statement, is used in conjunction with the Summary Judgment and Joinder Motions.[1]

Denials that the evidence cited in support of a particular statement does not support that statement, in instances where the evidence uncontrovertibly does support that statement, are treated as admissions. Denials without support or explanation are treated as admissions. The inclusion of statements in this Opinion that were challenged on admissibility grounds by the parties reflect a ruling that the admissibility challenge is overruled.

[1] Citations to these Undisputed Facts in subsequent sections of this Opinion will be made in the following format: UF ¶ __.

The following facts are not in material dispute except as noted below:

1. On May 7, 2002, Ferring filed Great Britain Patent Application No. GB0210397.6. Declaration of Zachariah J. Lloyd in Support of Allergan Defendants' Motion for Summary Judgment of Equitable Estoppel (hereinafter "Lloyd Decl.") Ex. 1 at 3; First Amended Complaint (hereinafter "FAC") ¶ 58.

2. The Great Britain 0210397.6 application disclosed a "pharmaceutical dosage form of desmopressin adapted for sublingual absorption," but did not claim any specific dosage ranges or serum concentrations of desmopressin. Lloyd Decl. Ex. 1 at 34-36.

3. The Great Britain 0210397.6 application did not list any inventors. Lloyd Decl. Ex. 1; FAC ¶ 58.

4. On September 20, 2002, Ferring, through its counsel, filed PCT application IB02/04036. Lloyd Decl. Ex. 2 at 1; FAC ¶ 59.

5. The PCT application IB02/04036 claimed the same subject matter as the Great Britain 0210397.6 application and

listed Dr. Fein among the inventors. Lloyd Decl. Ex. 2 at 31-34; FAC ¶ 59.

6. On May 6, 2003, Dr. Fein, through his counsel, filed PCT application US2003/014463. Declaration of Michael Adelman in Support of Allergan Defendants' Motion for Summary Judgment of Equitable Estoppel (hereinafter "Adelman Decl.") Ex. 22 at 1; FAC ¶ 68.

7. PCT application US2003/014463 was published as International Application WO 2004/041153 on May 21, 2004. Adelman Decl. Ex. 22 at 1.

8. On May 7, 2003, Ferring, through its counsel, filed PCT application IB03/02368. Adelman Decl. Ex. 23 at 1.

9. Ferring's PCT application IB03/02368 did not name Dr. Fein as an inventor and did not include claims directed to sublingual administration of desmopressin. Adelman Decl. Ex. 23 at 1; 32-34.

10. Ferring's PCT/IB03/02368 matured into U.S. patent application 10/513,437, with a filing date of May 7, 2003. Lloyd Decl. Ex. 11 at 2.

11. On November 12, 2003, Dr. Fein, through his counsel, filed continuation-in-part U.S. patent application

10/706,100 based off his PCT application US2003/014463. Adelman Decl. Ex. 24 at 1.

12. U.S. patent application 10/706,100 published as U.S. Patent Application 2004/0138098 A1 on July 15, 2004. Adelman Decl. 24 at 1.

13. On May 4, 2007, Dr. Fein, through his counsel, filed U.S. patent application 11/744,615 as a division of his previously filed U.S. patent application 10/706,100. Lloyd Decl. Ex. 7 at 2.

14. On July 15, 2008, Dr. Fein, through his counsel, filed U.S. patent application 12/173,074 as a continuation of his previously filed U.S. patent application 11/744,615. Lloyd Decl. Ex. 8 at 2.

15. On July 29, 2008, Dr. Fein's U.S. patent application 11/744,615 issued as U.S. Patent No. 7,405,203 ("the '203 patent"). Lloyd Decl. Ex. 7 at 2.

16. On June 18, 2009, Ferring, through its counsel, filed U.S. patent application 12/487,116 as a continuation of its previously filed U.S. patent application 10/513,437. Lloyd Decl. Ex. 10 at 2.

17. In a Preliminary Amendment dated November 6, 2009, Ferring amended U.S. Patent Application No. 12/487,116 to add claims directed to "[a]n orodispersible pharmaceutical dosage form of desmopressin acetate which disintegrates in the mouth within 10 seconds." Lloyd Decl. Ex. 12 at FERALL0001250. Ferring added a dependent claim that additionally limited this "orodispersible pharmaceutical dosage form of desmopressin acetate which disintegrates in the mouth within 10 seconds" to one "which is adapted for sublingual administration." Id.

18. Ferring did not add back Dr. Fein as an inventor when it reinserted a claim to U.S. patent application 12/487,116 for desmopressin adapted for sublingual administration. See Lloyd Decl. Ex. 10 at 2.

19. On July 14, 2009 Ferring's U.S. patent application 10/513,437 issued as U.S. Patent No. 7,560,429 ("the '429 patent"). Lloyd Decl. Ex. 11 at 2.

20. On August 25, 2009, Dr. Fein's U.S. patent application 12/173,074 issued as U.S. Patent No. 7,579,321 ("the '321 patent"). Lloyd Decl. Ex. 8 at 2.

21. On September 21, 2010, Dr. Fein's U.S. patent application 10/706,100 issued as U.S. Patent No. 7,778,761 ("the '761 patent"). Lloyd Decl. Ex. 9 at 2.

22. On May 24, 2011, Ferring's U.S. patent application 12/487,116 issued as U.S. Patent No. 7,947,654 ("the '654 patent"). Lloyd Decl. Ex. 10 at 2.

23. On October 12, 2010, Adriana Burgy of Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P., counsel of record for Ferring, filed a request for reexamination of Fein's '203 patent before the United States Patent and Trademark Office ("PTO"). Lloyd Decl. Ex. 5 at 37.

24. Defendants contend that Ms. Burgy did not disclose at the time that Ferring was responsible for the request for reexamination. Lloyd Decl. Ex. 5. Plaintiffs deny requesting that Ms. Burgy make ex parte reexamination request.

25. Ms. Burgy argued before the PTO that prior art anticipated or rendered obvious the independent claims of the '203 patent. Lloyd Decl. Ex. 5 at 20-36.

26. Dr. Fein had previously disclosed to the PTO U.S. Patent No. 5,498,598 ("Harris") and U.S. Patent No. 5,848,991 ("Gross"), relied upon by Ferring's counsel when prosecuting the '203 patent. Lloyd Decl. Ex. 5 at 10.

27. On January 19, 2011, the PTO rejected Ferring's request for reexamination of the '203 patent.

28. The PTO withdrew its obviousness objections after finding that the '203 patent demonstrated unexpected results.

29. On November 7, 2002, Ferring formally terminated Dr. Fein's consulting agreement. Adelman Decl. Ex. 21; Declaration of Dr. Seymour in Support of Allergan Defendants' Motion for Summary Judgment of Equitable Estoppel (hereinafter "Fein Decl.") ¶ 10; FAC ¶ 64.

30. On November 21, 2002, Dr. Fein's attorney, William Speranza, sent a letter to Ferring on Dr. Fein's behalf. Adelman Decl. Ex. 13.

31. In his letter, Mr. Speranza stated that Dr. Fein considered himself the inventor of a "sublingual, transmucosal route of delivery which affords a number of advantages . . . including enabling the effective use of formulations having reduced concentrations of desmopressin." Adelman Decl. Ex. 13 at 1.

32. Mr. Speranza asserted that Dr. Fein had not assigned any inventorship rights to Ferring during his consultancy, and therefore retained ownership rights in any patents that might develop from Ferring's patent applications. Adelman Decl. Ex. 13 at 1.

33. He also noted that Ferring had filed a PCT application naming Dr. Fein as an inventor, and asked for "copies of the PCT application and all related application papers already filed" and "all communications related to ongoing proceedings in the PCT or eventual national phase applications." Adelman Decl. Ex. 13 at 2.

34. On January 30, 2003, Mr. Speranza sent another letter to Ferring on Dr. Fein's behalf. Adelman Decl. Ex. 14.

35. In his letter, Mr. Speranza reiterated that Dr. Fein "possesse[d] ownership rights in the invention, the pending application therefor and any patents that may issue on his invention." Adelman Decl. Ex. 14 at 1.

36. Mr. Speranza informed Ferring that Fein intended to determine whether he would choose to "take steps independent of Ferring" to protect his patent rights, if Ferring did not acknowledge Fein's interests in the existing patent applications and if Ferring did not ensure that it would "take no actions which would in any manner affect, limit or compromise his inventorship rights and ownership interests" without obtaining Dr. Fein's consent. Adelman Decl. Ex. 14 at 1-2.

37. On April 9, 2003, Patricia Barclay, Ferring's counsel, sent a letter to Mr. Speranza. Adelman Decl. Ex. 15; FAC ¶¶ 65-66.

38. In her letter, Ms. Barclay advised Dr. Fein that Ferring decided to drop the feature "adapted for sublingual administration" from its PCT application because sublingual administration "does not in this context confer a delimitation i.e. novelty." Adelman Decl. Ex. 15.

39. As a consequence, Ms. Barclay stated that Ferring would remove Dr. Fein as an inventor from the PCT application. Adelman Decl. Ex. 15.

40. On April 17, 2003, Mr. Speranza sent an email to Ms. Barclay and Helle Aufeldt of Ferring. Adelman Decl. Ex. 16.

41. In his letter, Mr. Speranza acknowledged that Ferring was dropping Dr. Fein from its patent application, and made no objection to that decision. Adelman Decl. Ex. 16 at 1.

42. Mr. Speranza informed Ferring that Fein's alleged invention was "a sublingual, transmucosal route of delivery which affords a number of advantages in the efficacy and safety of desmopressin administration, including enabling the effective

use of formulations having reduced concentrations of desmopressin." Adelman Decl. Ex. 16 at 1.

43. Mr. Speranza informed Ferring that "Dr. Fein is planning to himself proceed with pursuing patent protection covering the sub-lingual administration route and the associated low dosage possibilities enabled by same which he invented, all at his own expense going forward and with the understanding that Ferring relinquishes any ownership claims thereto." Adelman Decl. Ex. 16 at 1.

44. On April 29, 2003, Ms. Barclay sent a letter to Mr. Speranza. Adelman Decl. Ex. 17.

45. Ms. Barclay acknowledged receipt of the April 17, 2003 letter. Adelman Decl. Ex. 17.

46. Ms. Barclay advised that Ferring believed that the "low dosage possibilities enabled by the sublingual administration route are already available in the public domain as exemplified by the enclosed abstract from Anne M Fjellestad-Paulsen's doctor's thesis published in 1996." Adelman Decl. Ex. 17. She added that "I cannot of course say now that Ferring will not make any claim as to ownership of any other material Dr Fein may include in any patent application as without seeing the text and knowing what claims for novelty or inventive steps he

has in mind I cannot be sure that this does not cover matters to which employees of the Ferring Group have contributed or regarding which Dr Fein is bound to us by terms of confidentiality." Id.

47. She stated that as a consequence, Ferring would not be pursuing claims directed at "the low dosage possibilities enabled by the sublingual administration route." Adelman Decl. Ex. 17.

48. Ms. Barclay provided Dr. Fein the application number for Ferring's 2002 Great Britain patent application. Adelman Decl. Ex. 17.

49. On December 9, 2004, Ms. Barclay sent a letter to Mr. Speranza. Adelman Decl. Ex. 18.

50. In her letter, Ms. Barclay stated that she was "truly surprised to see that Dr. Fein had proceeded with [his PCT] application to which we believe he has no entitlement and which in particular discloses information confidential and proprietary to Ferring to which Dr Fein had confidential access during his engagement as consultant." Allergan Ex. 18. Ms. Barclay added that "Ferring will take all necessary steps to protect its rights and interests." Id.

51. Ms. Barclay stated that PCT/US2003/014463 "contain[s] an invention to which we believe he has no entitlement and which in particular discloses information confidential and proprietary to Ferring to which Dr Fein had confidential access during his engagement as consultant." Id.

52. Ms. Barclay stated Ferring would "take all necessary steps to protect its rights and interests," and concluded by warning Dr. Fein that "if I do not receive a full and satisfactory explanation within 14 days of this letter we will commence formal action." Adelman Decl. Ex. 18.

53. On December 14, 2004, Mr. Speranza sent two letters to Ms. Barclay. Adelman Decl. Ex. 19; Adelman Decl. Ex. 20.

54. In the first letter of December 14, 2004, Mr. Speranza reminded Ferring that his April 17, 2003 email informed Ferring that "Fein is planning to himself proceed with pursuing patent protection covering the sub-lingual administration route and the associated low dosage possibilities enabled by same." Adelman Decl. Ex. 19 at 1.

55. Mr. Speranza's letter referred to the "dealings and communications throughout 2003" with Ferring that "made

clear that Ferring made no claim to low dosage desmopressin as its invention." Adelman Decl. Ex. 19 at 2.

56. Mr. Speranza concluded his letter by saying, "[w]e trust this response will put this matter to rest." Adelman Decl. Ex. 19 at 2.

57. Later the same day, Mr. Speranza sent a follow up letter referencing Dr. Fein's continuation-in-part U.S. patent application. Adelman Decl. Ex. 20 at 2.

58. Following this final exchange of correspondence between Ferring and Dr. Fein's counsel, Ferring took no direct action on Dr. Fein's patent applications, and later patents, for over seven years.

59. On the basis of his communications with Ferring, Dr. Fein inferred that he was free to independently pursue patent protection for his invention without interference. Fein Decl. ¶ 12.

60. In August 2003, Dr. Fein was the sponsoring signatory of a clinical study titled "CNF Desmo PK 200301." Adelman Decl. Ex. 25 at 1.

61. CNF Desmo PK 200301 purportedly tested the antidiuretic effect of three low doses of desmopressin

administered via intravenous solution in healthy volunteers. Adelman Decl. Ex. 25 at 3.

62. In November and December 2004, Dr. Fein was the sponsoring signatory of a clinical study titled "CNF Desmo SC 200401." Adelman Decl. Ex. 26 at 1.

63. CNF Desmo SC 200401 purportedly tested the antidiuretic effect of three low doses of desmopressin administered via subcutaneous infusion in healthy volunteers. Adelman Decl. Ex. 26 at 3.

64. Herschkowitz testified that Dr. Fein and his colleagues at CNF Pharma, LLC spent approximately $380,000 to conduct the CNF Desmo PK 200301 and CNF Desmo SC 200401 studies, as reflected in a draft submission to the International Trade Commission ("ITC"). Adelman Decl. Ex. 27 (Herschkowitz Dep. at 299:20-300:15).

65. In 2005, Dr. Fein provided the correspondence between Mr. Speranza and Ms. Barclay to his business partners' counsel as they conducted due diligence in anticipation of forming a new company, Serenity Pharmaceuticals Corporation, for the purposes of commercially developing Dr. Fein's invention. Adelman Decl. Ex. 27 (Herschkowitz Dep. at 53:5-57:20).

66. Dr. Herschkowitz relied upon this correspondence in deciding to proceed with the commercialization of Dr. Fein's invention. Adelman Decl. Ex. 27 (Herschkowitz Dep.) at 57:16-20.

67. Dr. Fein and others subsequently formed Serenity Pharmaceuticals Corporation. Adelman Decl. Ex. 33 at 1; FAC ¶ 76.

68. In early 2007, Dr. Fein and others formed Reprise Biopharmaceuticals, LLC. Lloyd Decl. Ex. 3 at 1; FAC ¶ 78.

69. Dr. Fein testified that he transferred his intellectual property rights related to his desmopressin invention to Reprise. Adelman Decl. Ex. 29 (Fein Dep. at 292:14-293:4).

70. On December 10, 2007, Serenity had a pre-IND meeting with the FDA and the FDA agreed to a 505(b)(2) NDA pathway for Serenity's desmopressin treatment. Adelman Decl. Ex. 34 at 11.

71. In early 2008, Serenity conducted a Phase I clinical trial of its nasal spray desmopressin product. Adelman Decl. Ex. 34 at 47.

72. On August 4, 2008, Serenity issued a press release announcing that it had filed its IND to initiate Phase I clinical testing. Lloyd Decl. Ex. 4.

73. In late 2008, Serenity conducted a Phase II clinical study. Adelman Decl. Ex. 34 at 47.

74. From 2009 to 2010, Serenity conducted a Phase III study. Adelman Decl. Ex. 35 at 1.

75. On May 13, 2008, in response to an inquiry from Allergan, Dr. Fein identified the Speranza correspondence as establishing his freedom to practice his patents without interference from Ferring in an email to Herschkowitz. Adelman Decl. Ex. 32. That correspondence was not sent to Allergan. Allergan Estoppel Reply Mem. 9-10.

76. On March 31, 2010, Reprise and Serenity entered into agreements with Allergan to develop and commercialize a desmopressin product known as SER120. Adelman Decl. Ex. 30; Adelman Decl. Ex. 31.

77. As part of the March 31, 2010 agreements, Reprise and Serenity assigned all interests in Dr. Fein's patents to Allergan. Adelman Decl. Ex. 30 at 27; Adelman Decl. Ex. 31 at 16-23.

78. As part of the March 31, 2010 agreements, Reprise and Serenity represented and warranted that they held exclusive and uncontested rights to Dr. Fein's patents. Adelman Decl. Ex. 30 at 15-17; Adelman Decl. Ex. 31 at 67-72.

79. The March 31, 2010 agreements included warranties from Reprise and Serenity that there was not even a threat of litigation from any third party regarding Dr. Fein's patents. Adelman Decl. Ex. 30 at 17; Adelman Decl. Ex. 31 at 68.

80. Pursuant to the March 31, 2010 agreement, Allergan made an upfront payment of $43 million to Serenity for the rights to Dr. Fein's patents. Adelman Decl. Ex. 31 at 51, Ex. 1.8.

81. March 31, 2010 agreement required Allergan to assume limited responsibility for certain development costs. Adelman Decl. Ex. 31 at 31-33.

82. If Serenity were able to gain regulatory approval, if the product met certain sales goals, and if certain other conditions were established, Allergan could make milestone payments totaling over $300 million. Adelman Decl. Ex. 31 at 51-53.

83. On April 1, 2010, Serenity and Allergan released a press release announcing their agreement to develop SER120, a Phase III investigational drug for treatment of nocturia. Adelman Decl. Ex. 35.

84. From 2003 to 2012, Defendants (including Drs. Fein and Nardi, Serenity Pharmaceuticals Corporation, Serenity Pharmaceuticals, LLC, and Allergan) invested over $60 million dollars in design, clinical research, and manufacturing, among other expenses, to develop a desmopressin product protected by Dr. Fein's patents. Adelman Decl. Ex. 27 (Herschkowitz Dep.) at 298:15-299:19.

The Applicable Standard

Summary judgment is appropriate only where "there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). A dispute is "genuine" if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). The relevant inquiry on application for summary judgment is "whether the evidence presents a sufficient

disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." Id. at 251-52. A court is not charged with weighing the evidence and determining its truth, but with determining whether there is a genuine issue for trial. Westinghouse Elec. Corp. v. N.Y. City Transit Auth., 735 F. Supp. 1205, 1212 (S.D.N.Y. 1990) (quoting Anderson, 477 U.S. at 249).

The Elements for Equitable Estoppel Are Met

A defendant asserting equitable estoppel bears the burden of establishing the following three elements by a preponderance of the evidence: (1) the plaintiff, through misleading conduct, led the defendant to reasonably infer that the claimant does not intend to enforce his claim—"conduct" may include specific statements, action, inaction, or silence where there is a duty to speak; (2) the defendant relied upon that conduct; (3) due to its reliance, the defendant will be materially prejudiced if the claiming party is allowed to proceed with its claim. Pannu v. Iolab Corp., 96 F. Supp. 2d 1359, 1368 (S.D. Fla. 2000) (citing A.C. Aukerman Co. v. R.L. Chaides Constr. Co., 960 F.2d 1020, 1042-43, 1046 (Fed. Cir.

1992) (en banc)). "Silence alone is not sufficient . . . to give rise to estoppel." Meyers v. Asics Corp., 974 F.2d 1304, 1308 (Fed. Cir. 1992).

The purportedly misleading conduct at issue here stems mainly from the series of letters and emails exchanged between Ms. Barclay, on Ferring's behalf, and Mr. Speranza, on Dr. Fein's behalf, from 2002 to 2004. See, generally, UF ¶¶ 29-58. In 2002 and 2003, Dr. Fein told Ferring that he was the inventor of the low-dose/sublingual improvements to desmopressin.

In his November 2002 letter to Ferring, Dr. Fein asserted that he invented a "sublingual, transmucosal route of delivery which affords a number of advantages . . . including enabling the effective use of formulations having reduced concentrations of desmopressin." Id. Fein reiterated that he retained the rights to this invention, separate from Ferring, in at least three separate communications between November 2002 and April 2003. See, e.g., UF ¶¶ 32, 35, 43, 54. In 2003, he told Ferring that he was applying for patents directed to those improvements to desmopressin technology. UF ¶ 40. In 2004, Ferring threatened Dr. Fein with legal action unless he responded to Ferring's accusations that his patent applications

were improper, stating "if I do not receive a full and satisfactory explanation within 14 days of this letter we will commence formal action." UF ¶ 52. Dr. Fein responded, and explained his position to Ferring, asserting that: he had disclosed his intention to pursue his own patents in his April 17, 2003 email; Ferring had acknowledged receipt of that email in its April 29, 2003 letter; and their "dealings and communications throughout 2003" had "made clear that Ferring made no claim to low dosage desmopressin as its invention." UF ¶¶ 54-55. He concluded: "We trust this response will put this matter to rest." UF ¶ 56. Subsequently, Ferring made no response and took no further action for over seven years, while Defendants expended significant resources prosecuting, developing and commercializing Dr. Fein's patents. See, generally, UF ¶¶ 57-84.

As Ferring notes in its opposition brief, the correspondence here referenced a PCT application for "a sublingual, transmucosal route of delivery that enabled reduced dosages," rather than any of the three actual patents-in-suit. Pls.' Estoppel Mem. in Opp'n 17. Allergan, in its reply, contends that "[t]he fact that the misleading conduct and reliance occurred or began before the patent issued does not

render the doctrine of equitable estoppel inapplicable." Allergan's Estoppel Reply Mem. 5.

Whether misleading conduct may precede an actual patent is a close question. Commentators have noted this conflict in the case law. Compare Raymond T. Nimmer and Jeff C. Dodd, Modern Licensing Law, § 10:13 (2014) ("[T]he Federal Circuit held that silence or misleading statements with respect to an unissued patent would not give rise to estoppel. This rule does not seem to have been generally followed and we do not believe that it correctly states the law of estoppel.") with Robert A. Matthews, Jr., Annotated Patent Digest, 2 § 11:194 (2015) ("Since patent rights are not effective until the patent issues, a patentee's conduct towards an accused infringer at a time before the patent issued, may not give rise to an estoppel.").

Several post-Aukerman Federal Circuit opinions appear to require an issued patent in order to apply the doctrine. In Ricoh Co. v. Nashua Corp., the Federal Circuit held that a patent owner cannot be estopped for failing to speak up with respect to a pending patent. 185 F.3d 884 (Fed. Cir. 1999) (after noting that "[t]he law is clear that a party can be

misled by inaction," distinguishing "between inaction in light of an issued patent [that satisfies the misleading action prong] . . . and inaction in light of a pending patent application [that does not]."). Similarly, in Radio Sys. Corp. v. Lalor, one of the issues on appeal before the Federal Circuit was whether equitable estoppel could be applied to a patent that had not been issued at the time of the misleading conduct. 709 F.3d 1124, 1131 (Fed. Cir. 2013). There, one patent was issued prior to the misleading conduct while a second continuation-in-part patent was issued several years after the misleading conduct. Id. at 1126. The Federal Circuit held that the lower court abused its discretion in holding that equitable estoppel applied to the later patent, holding that "[r]egardless of whether the [later] patent claims are supported by the subject matter in the [earlier] patent—and therefore entitled to claim priority to its filing date—the patents contain claims of different scope. Quite simply, the [later] patent claims could not have been asserted . . . until those claims issued." Id. Finally, in Meyers v. Asics Corp., the Federal Circuit held that no equitable estoppel could apply to two of the three asserted patents against one of the accused infringers since the patentee had no contact with the accused infringer after the two patents issued, therefore, he "could not have communicated acquiescence,

or threatened litigation with respect to [the accused infringer]'s alleged infringement of these patents." 974 F.2d 1304, 1309 (Fed. Cir. 1992).

However, "the Federal Circuit, both before and after Aukerman, has applied the equitable estoppel defense in circumstances in which there was not an issued patent at the time of the misleading communication." Rambus, Inc. v. Infineon Technologies AG., 326 F. Supp. 2d 721, 738 (E.D. Va. 2004) (citing MCV, Inc. v. King-Seeley Thermos Co., 870 F.2d 1568 (Fed. Cir. 1989) and Wang Laboratories, Inc. v. Mitsubishi Electric Corp., 103 F.3d 1571 (Fed. Cir. 1997) in support of the the proposition that "[t]he mere fact that, at the time of the misleading communication (whether by conduct or inaction), a patent has not been issued should not permit the actor, upon the defendant's proof of the other elements of equitable estoppel, to escape the consequences of its misleading communications after the patent has in fact been issued."). Most recently, the Federal Circuit has also applied the doctrine in instances where the misleading communication did not identify a specific infringing product and did not explicitly threaten brining an infringement action. See Aspex Eyewear Inc. v. Clariti Eyewear, Inc., 605 F.3d 1305, 1310 (Fed. Cir. 2010).

Ultimately, "equitable estoppel is not limited to a particular factual situation nor subject to resolution by simple or hard and fast rules," and this issue must be decided on the unique facts of each case measured against the Aukerman test. See Aukerman, 960 F.2d at 1041. In this case, Ferring's inaction does give rise to an estoppel claim. To be sure, Ferring pled claims under 35 U.S.C. § 256 for correction of the named inventor of the three patents-in-suit, and a condition precedent to Ferring's Section 256 claim is issuance of the patents. See Hor v. Chu, 699 F.3d 1331, 1335 (Fed. Cir. 2012). However, in his correspondence with Ferring, Mr. Speranza explicitly referred to "low dosage" applications of desmopressin as Fein's inventions. See, e.g., UF ¶¶ 43, 54-55. Ferring's response to Fein's claim of inventorship was not that the low-dosage invention was Ferring's intellectual property, but that it was not patentable at all, and that Ferring would no longer be pursuing claims directed toward it. UF ¶ 51. Ferring's present application to correct inventorship contradicts its earlier position in the Speranza correspondence. The low-dosage invention as described in the PCT at issue in the Speranza correspondence is the same subject matter detailed in the patents-in-suit, down to the specific numerical quantity of

desmopressin to be used. See, e.g., Lloyd Exs. 1-2, 7-9. Consequently, this case is distinguishable from Radio Systems, where the patent not covered by equitable estoppel was held to contain claims "different in scope" from those of the patents that were the focus of the misleading communication. See Radio Systems, 709 F.3d at 1131.

Despite having threatened immediate legal action with respect to the patent application, Ferring did not disagree or otherwise challenge Mr. Speranza's assertion that low dosage development was Fein's intellectual property. Ferring was aware of two Fein patent applications that include claims for low desmopressin doses and low desmopressin plasma concentration levels. Ferring's December 9, 2004 letter reflects that the parties were discussing Dr. Fein's 2003 PCT application. UF ¶¶ 49-52. Then, on December 14, 2004, Mr. Speranza sent Ms. Barclay Dr. Fein's first U.S. patent application. UF ¶ 53. Both of those applications contained claims for specific low doses and specific low plasma concentration levels. See Adelman Decl. Exs. 20, 22. In sum, Ferring's inaction satisfies the misleading communication prong under Aukerman.

The reliance prong is also satisfied as to all Defendants. Reliance can be demonstrated through evidence of activities premised on the patent's validity, such as preparing a business plan and making capital investments. See, e.g., Frugoli v. Fougnies, No. CIV 02-957-PHX R, 2004 WL 3372012, at *10 (D. Ariz. Aug. 25, 2004); Stewart & Stevenson Servs., Inc. v. Serv-Tech, Inc., 794 F. Supp. 202, 206 (S.D. Tex. 1992) aff'd, 996 F.2d 318 (Fed. Cir. 1993) (preparing a business plan and making capital investments are evidence of reliance). Dr. Fein relied upon Ferring's inaction by spending several years commercializing his invention, including research and investments by both himself and the entities he helped form, Reprise and Serenity. He also asserted unchallenged ownership over the inventions to the companies that acquired his intellectual property based on Ferring's misleading silence. UF ¶ 59.

Reprise is a holding company with five members, including Drs. Fein and Nardi, created for the sole purpose of holding Fein's intellectual property. See UF ¶¶ 68-69. Dr. Fein's knowledge of Ferring's misleading conduct is imputed to Reprise and to Dr. Nardi. See Forest Labs., Inc. v. Abbott Labs., No. 96-CV-159-A, 1999 WL 33299123, at *9 (W.D.N.Y. June

23, 1999) aff'd, 239 F.3d 1305 (Fed. Cir. 2001) (misleading conduct directed at a doctor before he formed a small, closely held pharmaceuticals development company was considered by the court when determining whether the company had been misled).

When the patent rights were assigned to Allergan, Serenity warranted to Allergan that it had full rights to the patents. UF ¶¶ 78-79. Until Ferring began asserting its inventorship claims, none of the Defendants had reason to believe Ferring would dispute inventorship of the low-dosage inventions.

In its opposition on this prong, Ferring contends that Reprise, Serenity, Dr. Nardi and Allergan never received the Speranza correspondence and that, even if they had, they cannot rely on Ferring's statements to Fein to establish their own reliance on Ferring's alleged conduct. See Pls.' Estoppel Mem. in Opp'n 12-13; Pls.' Joinder Mem. in Opp'n 2-5. However, Dr. Fein was unquestionably aware of the Speranza correspondence, and he is the person whose inventorship is being challenged. Allergan and the other corporate Defendants, as the entities that purchased Dr. Fein's inventions, stand in his shoes for the purposes of reliance. See Radio Systems, 709 F.3d at 1130-31

(affirming summary judgment because "equitable estoppel applies to successors-in-interest where privity has been established"). That Allergan, Reprise and Serenity are not the corporate successor-in-interest in the sense that they merged with or completely acquired of any of the other Defendants is of no moment, because the Federal Circuit did not "explicitly or implicitly narrowly define a successor or privity as requiring a complete transfer of a corporation or financial control." Enel Co., LLC v. Schaefer, No. 12-CV-1369-IEG WMC, 2013 WL 5727421, at *4 (S.D. Cal. Oct. 22, 2013) (citing to Radio Systems). Here, the transfer of Fein's rights to Reprise, Serenity and Allergan make those entities successors-in-interest with respect to the issue of reliance.

Finally, the prejudice prong is satisfied under these facts. "Prejudice may be shown by a change of economic position flowing from actions taken or not taken by" the party asserting equitable estoppel. Aspex, 605 F.3d at 1312. Non-recoupable capital investments, such as manufacturing and marketing, are the clearest evidence of material economic prejudice to a defendant that is asserting equitable estoppel. Wafer Shave, 857 F. Supp. at 125; see also Scholle Corp. v. Blackhawk Molding Co., Inc., 133 F.3d 1469, 1472 (Fed. Cir. 1992) (finding

sufficient economic prejudice to justify summary judgment on equitable estoppel grounds because the defendant had invested $700,000 in tooling and machinery for manufacture of patented technology with respect to which plaintiff had remained silent after initially leveling an accusation of infringement). Defendants can also demonstrate material prejudice by showing that the present suit would result "in damages which likely would have been prevented by an earlier suit." ABB Robotics, Inc. v. GMFanuc Robotics Corp., 52 F.3d 1062, 1065 (Fed. Cir. 1995) (quoting Aukerman, 960 F.2d at 1033). The patents need not be issued for a defendant to show prejudice; expenditures to procure a patent are also economic prejudice. ABB Robotics, 52 F.3d at 1065.

Since Dr. Fein and Ferring ended their collaboration in November 2002, Defendants have invested tens of millions of dollars to secure patent protection for Dr. Fein's desmopressin invention and pursue associated commercial opportunities. See, generally, UF ¶¶ 80-89. After Dr. Fein's counsel made contact with Ferring and informed it of Dr. Fein's intent to pursue his patents independently, Dr. Fein, via CNF Pharma, ran two clinical trials at an out-of-pocket expense of approximately $380,000. UF ¶ 64. After the proof-of-concept studies provided

data to support the prosecution of Dr. Fein's patents, Dr. Fein and Mr. Herschkowitz helped to form Serenity. UF ¶ 67. Serenity, in turn, raised millions of dollars in funding from investors and used those funds to clinically develop a new low-dose desmopressin treatment. UF ¶ 84. Allergan has invested over $43 million to acquire the patents-in-suit. UF ¶ 80. If Drs. Nørgaard and Senderovitz were added as co-inventors to Dr. Fein's patents, Allergan would be unable to prevent other competitors from selling infringing products if these competitors obtain a license from Ferring or if Ferring would not agree to join Allergan's infringement suit as a co-owner. See, e.g., Schering Corp. v. Roussel-UCLAF SA, 104 F.3d 341, 344 (Fed. Cir. 1998). In lieu of a financial investment in Reprise, Dr. Nardi committed several years of work to helping develop low dosage desmopressin and has a substantial ownership stake in Reprise, which would be prejudiced by Ferring's claim. See Declaration of Pier DeRoo, Esq. in Support of Ferring's Opposition to Defendants' Motion for Summary Judgment on Equitable Estoppel (Nardi Dep.) 279:22-282:10.

If Dr. Fein were no longer a named inventor, Allergan would not only lose the ability to prevent other competitors from practicing Dr. Fein's patents, but it would be selling

desmopressin products at the risk of an infringement suit from Ferring. Serenity and Reprise, and therefore their shareholders such as Drs. Fein and Nardi, stand to lose millions of dollars in non-recoverable investments if Ferring is successful in this action. This is sufficient to establish prejudice. Cf. IXYS Corp. v. Advanced Power Tech., Inc., 321 F. Supp. 2d 1156, 1164 (N.D. Cal. 2004). Moreover, Reprise would not have entered into a contract to license its intellectual property to Serenity and Allergan but for its belief that the intellectual property it held would not be challenged by Ferring.

These facts are an adequate basis upon which to find prejudice. That Allergan refused to provide testimony on its post-acquisition development expenditures of the patents-in-suit does not call into question the fact that it has already invested $43 million to acquire those rights. Defendants adequately demonstrated that they pursued development of a desmopressin treatment while reasonably relying on Ferring's acquiescence to Dr. Fein pursuing his own patents, as required under Federal Circuit precedent. See id. at 1312-13.

Consistent with above analysis, the non-Allergan Defendants' joinder motion is also granted. Ferring's principle

argument in opposition to the joinder motion is Allergan's 56.1 statement does not adequately establish the non-Allergan Defendants' right to equitable relief. See, generally, Pls.' Joinder Mem. in Opp'n 2-5. Under these facts, however, the non-Allergan Defendants have established that Ferring engaged in misleading conduct by first threatening suit and then taking no further action, that Dr. Fein, and derivatively, the non-Allergan Defendants, relied on Ferring's silence, and that the non-Allergan Defendants were economically prejudiced as a result.

The Court has also considered and rejects Ferring's unclean hands arguments. Cf. Pls.' Estoppel Opp'n 23-25. The Court has previously addressed Ferring's fraudulent concealment claim and dismissed allegations that Dr. Nardi's use of documents from his personal computer was illegitimate.

Ferring's allegations of witness collusion are likewise unpersuasive. Id. at 24. That Allergan points to oral conversations as proof of actions of inventorship is not, as Ferring would have it, objectionable or grounds for denial of the summary judgment motion. The facts are what they are, and neither party can be faulted for the absence of documentation

substantiating an assertion. The only specific example of witness collusion to which Ferring refers is a 2012 meeting between Dr. Fein, Dr. Nardi and Ms. Cheng, organized by Allergan's attorneys in preparation for proceedings in The Hague. Id. Ferring points to the fact that Ms. Cheng and Dr. Fein subsequently altered their witness statements as proof that the meeting was collusive in nature. Id. However, an equally plausible explanation for the alterations is the review of additional documents, which Ferring concedes occurred during the meeting. See id. Ferring has not demonstrated anything nefarious by this set of facts.

Finally, the Court is satisfied that Allergan's misstatement that it reviewed the text of the Speranza correspondence during its diligence process leading up the March 2010 agreements was inadvertent rather than the type of particularly egregious conduct warranting denial of equitable relief.

Granting Defendants' Summary Judgment and Joinder Motions terminates this action, and consequently, renders moot the Motion to Compel and the Confidentiality Motion.

Conclusion

For the foregoing reasons, Defendants' motions for summary judgment and joinder are granted. The remaining Motion to Compel and Confidentiality Motion are rendered moot. The parties shall meet and confer and provide the Court with a proposed redacted version of this Opinion within a week.

It is so ordered.

New York, NY

August , 2015

ROBERT W. SWEET
U.S.D.J.

Conclusion

For the foregoing reasons, Defendants' motions for summary judgment and joinder are granted. The remaining Motion to Compel and Confidentiality Motion are rendered moot. The parties shall meet and confer and provide the Court with a proposed redacted version of this Opinion within a week.

It is so ordered.

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August 31, 2015

ROBERT W. SWEET
U.S.D.J.